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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/633,577	08/05/2003	Marc Freyfus	0508-1042-1	5205

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EXAMINER	
PATTERSON, CHARLES L JR	
ART UNIT	**PAPER NUMBER**
1652	

DATE MAILED: 06/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/633,577	FREYFUS ET AL.	
	Examiner	Art Unit	
	Charles L. Patterson, Jr.	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-17 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-17 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/762,481.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

It is noted that the oath of the instant application lists the first inventor as "Marc Freyfus", as was the case in the parent application, instead of "Marc Dreyfus". In the parent application apparently a corrected filing receipt was issued correcting this name but no such corrected filing receipt has been issued in this application. As it now stands the name in the computer that will appear on any patent issued for this application is "Freyfus". Applicant should correct this obvious error appropriately with a new oath.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,632,639. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are simply generic claims to the specific claims in the instant patent. The generic claims would be obvious over the specific claims in the instant patent.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6, 8-15, 17-19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for mutations deleting the amino acids from 586-1061 of the RNase E, does not reasonably provide enablement for claims of the scope of the instant claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The specification teaches that the mutant of RNase E containing G2196T, which deletes amino acids 586-1061 (476 amino acids), and the "*rne131*" mutant have reduced degrading activity on mRNA but can still grow and process rRNA. In applicants' response to this rejection in the parent application, applicants refer to page 15, lines 4-11 of the specification and the paragraph spanning pages 3920-3921 of Kido, et al. The recitation on page 15 states that the *rne131* mutation is the same as the *smbB131* mutation in Kido, et al. and that this "is a deletion of 2 nucleotides at the 586th codon, causing a reading frame shift followed by a stop, after a supplemental translation of 32 codons without relation to the normal sequence of Rnase E". The instant paragraph of Kido, et al. states that the mutation encodes "a truncated polypeptide of 616 amino acids residues followed by additional 32 residues beyond the deletion". These two recitations are inconsistent. The specification states that there is a deletion of 2 nucleotides from codon 586 followed by 32 codons. This would be a total of apparently 617 amino acids, omitting residue 586 from the counting. Kido states that there are 616 amino acids followed by an additional 32 residues, for a total of 648. It is noted that

the specification does not state exactly which 2 nucleotides of the 586th codon are deleted, and that may make a difference in the operability of the mutate. This is completely inconsistent and thus one of ordinary skill in the art reading the instant specification would not know exactly what the *rne131* mutation was. Therefore, because the exact mutation in *rne131* cannot be ascertained with any assurance, the claims should be limited to the scope indicated *supra*, i.e. a mutation deleting residues 586-1061.

The mutant G2196T introduces a stop codon at amino acid residue position 586 such that the RNase E produced has amino acids 586-1061 deleted. This (and the *rne131* mutation) are shown by the instant specification to reduce or eliminate mRNA degradation but not to affect cell growth or rRNA processing. The instant claims are drawn to any and all *E. coli* possessing this phenotype, to substitution or deletion of one or several nucleotides from the C-terminal portion of RNase E or to the deletion of the last 563 amino acids from RNase E. The specification does not teach one of ordinary skill that embodiments of this scope will have the phenotype claimed and therefore one of ordinary skill in the art would not know how to make *E. coli* strains that meet the requirements of the instant claims other than the G2196T mutant.

The recitation in the paragraph spanning pages 18-19 is not understood. How can the mutation G2196T not produce any phenotype change if it no longer degrades mRNA when the wild-type does? Regarding the statement in the claims (e.g. claim 6) and the specification that up to 563 amino acids can be deleted and that this supposedly equates with the elimination of positions 1935-3623, an examination of SEQ ID NO:1 shows that if residue position 1935-3623 are deleted then 562 amino acids are deleted, not 563. An explanation is required.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3-8, 10-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kido, et al. (AC). The instant reference teaches in the abstract that the *rne* mutants disclosed by the reference lack the C-terminal portion and that the mutations increase the half-lives of mRNA. On page 3923, lines 8-10 of the first full paragraph it is taught that the mutants are able to grow normally. It would have been obvious to one of ordinary skill in the art to delete the C-terminal portion in order to produce mutants that increase the half-life of mRNA (i.e. that no longer possess degrading activity for mRNA). It is maintained that anything else in the instant claims, such as exogenous inducible expression systems, would have been obvious to the ordinary artisan in view of well known and used processes in the prior art, absent unexpected results. Only claims 2 and 9 were not rejected because they state that the activity of rRNA maturation is preserved and apparently the instant reference does not teach this. The instant reference teaches using *rne* mutants lacking "a carboxyl-terminal half" but apparently do not teach which specific residues are deleted. Therefore all of the instant claims are deemed to read on these teachings.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles L. Patterson, Jr., PhD, whose

telephone number is 571-272-0936. The examiner can normally be reached on Monday - Friday from 7:30 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Charles L. Patterson, Jr.
Primary Examiner
Art Unit 1652

Patterson
June 17, 2005